

## **REMARKS**

Applicants have the following comments in support of this amendment.

### **I. Claim Amendments - Reference To The Disclosure**

In order to further clarify the claimed sanitizing compositions of the present application, Applicants are amending independent Claims 1 and 9 (dependent Claims 8 and 16 are then being canceled without prejudice or disclaimer). In particular, these claims have been amended to clarify that the claimed compositions are directed to liquid sanitizing compositions (this being the feature of dependent Claims 8 and 16).

Therefore, the amendments to the claims have not added any new matter and are clearly supported by the original application as filed. Hence, it is respectfully requested that this amendment be entered and considered at this time.

### **II. Claim Rejections - 35 U.S.C. §103**

#### **A. Scholz (U.S. 5,908,619)**

In the Office Action, the Examiner rejects Claims 1, 5-10, and 13-16 under 35 U.S.C. §103(a) as being unpatentable over Scholz (U.S. 5,908,619). This rejection is respectfully traversed.

While Applicants traverse this rejection, as explained above, in order to advance the prosecution of this application and clarify the claimed invention, Applicants are amending Claims 1 and 9 to recite that the claimed invention is directed to liquid sanitizing compositions.

Previously, in the Final Rejection of June 24, 2008, the Examiner withdrew the prior §103 rejection over Scholz and acknowledged that Scholz failed to disclose the claimed compositions (see

e.g. third paragraph on p. 2 and second paragraph on p. 3 of the Final Rejection). The Examiner then turned to McLeod et al. (Intern. J. Parasitology) for certain data on inhibition of bacterial growth (i.e., bacteriostatic properties) of triclosan at certain levels, and combined McLeod with Scholz to reject the claims of the present application.

In response to this Final Rejection, in Amendment B (filed January 19, 2009), Applicants pointed out that the cited IC50 levels of McLeod (i.e., half maximal inhibitory concentrations, which correspond to the levels of test agent necessary to achieve a 50% inhibition of growth *in vitro*) were *unrelated* to bactericidal levels (i.e., levels that kill all exposed organisms in bactericidal compositions). Hence, the combination of McLeod with Scholz does not disclose or suggest the claimed invention.

In the present Office Action, the Examiner has now dropped McLeod but is again rejecting the claimed subject matter over Scholz alone. In light of the prior acknowledgment of the Examiner regarding the inadequacies of Scholz *viz-a-viz* Applicants' pending claims, this rejection is quite surprising. Nonetheless, as explained below, Scholz still fails to disclose or suggest the claims of the present application..

In the explanation of the current §103 rejection, the Examiner contends that Scholz discloses use of triclosan as a second antimicrobial and discloses that the microbial may be at a concentration of 0.05% to 1% by weight (citing column 17, lines 55-56 in Scholz).

However, Applicants note that the entire paragraph at column 17, lines 55-56 in Scholz refers only to chlorhexidine and certain derivatives thereof, including chlorhexidine digluconate (CHG). Chlorhexidine and these derivatives are completely unrelated to triclosan, and thus have no bearing on the properties of triclosan. Specifically, the cited passage states:

“...The most preferred antimicrobial is chlorhexidine digluconate (CHG). CHG is preferably present at a concentration of about 0.05-5.0%, more preferably about 0.1-3%, even more preferably about 0.25-2%, and most preferably about 0.5-1%, by weight....” (column 17, lines 54-58)

Hence, the cited levels apply to CHG, not triclosan. There is no reason that such concentrations should be applied to triclosan. Scholz provides no disclosure or suggestion that such levels can be applied to triclosan.

Further, in the entire disclosure, Scholz makes only a single reference to triclosan, in the paragraph immediately preceding this passage, where triclosan is included in a lengthy Markush group of antimicrobials:

“Antimicrobials

“In addition to the lower alcohols present in the composition of the present invention, other antimicrobials (i.e., a secondary antimicrobial agent) may be added to enhance the antimicrobial action of the compositions of the present invention..... Suitable additional antimicrobials include ... triclosan.... In order to reduce chances for irritation and yet maintain efficacy, the antimicrobial level should be adjusted to the minimum level which maintains a low bacteriological count for 6 and most preferably for 12 hours after application.” (column 17, lines 30-49)

Notably, Scholz does not provide any clue regarding an appropriate levels of triclosan in the composition (or that the later recited levels for CHG should apply to triclosan). The Examiner appears to recognize this as he admits that Scholz does not teach that triclosan is present in an amount greater than 0% and equal or less than 0.04% (and in fact, there is no disclosure or suggestion of this concentration for any antimicrobial in Scholz). The Examiner, however, contends that “it would have been obvious to use 0.04% of triclosan in the composition since Scholz teaches that about 0.05% of the antimicrobial agent can be present.” Applicants respectfully disagree.

More specifically, as explained in the specification of the present application, the claimed sanitizing composition achieves an unanticipated synergistic bactericidal activity. See e.g.

paragraphs [0037], [0038], [0043], [0045], [0057] and [0060], along with the assay data shown in Tables 1 and 4 of the present application. These passages clearly show that the claimed compositions have bactericidal properties and achieve an unanticipated synergistic bactericidal result. There is no recognition in Scholz of this synergistic bactericidal result. In fact, this is an unexpected result.

Furthermore, to the extent that Scholz provides any prescription for level of the antimicrobial component (i.e. CHG), it is predicated for the lower level of the concentration on a “more is better” line of reasoning, at least as far as any specific levels are concerned. As noted *supra*, Scholz specifies levels of CHG that are “at about 0.05-5.0%, more preferably about 0.1-3%, even more preferably about 0.25-2%, and most preferably about 0.5-1%, by weight.” (column 17, lines 54-58). Hence, to reach the preferred level, the lower level of the concentration is increasing.

Thus, in contrast to the Examiner’s suggestion that it would be obvious to extrapolate downward from this disclosure to Applicants’ claimed level of 0-0.04% of triclosan, Scholz does not specify any levels for triclosan, and clearly teaches that any such extrapolation from the levels listed (for CHG) should be at 0.05% or higher, and most preferably much, much higher or provide any reason or suggestion for such a downward extrapolation. In fact, Scholz provides absolutely no reason for using the lower claimed level of triclosan (or any antimicrobial agent).

Given these teachings in Scholz, it is highly unlikely that one of ordinary skill in the art would select triclosan as an antimicrobial agent and then, contrary to Scholz’s teachings on CHG, select a level of triclosan substantially lower than the lowest limit suggested by Scholz (such limit again made only in reference to CHG). Instead, since Scholz teaches more is better, the only possible conclusion would be that this skilled practitioner would be led to use antimicrobial at a level

much higher than 0.5%, such levels not being “within the scope of ‘about’” as suggested by the Examiner on p. 3 of the Office Action.

Applicants further note that the claimed levels of triclosan are counter to those suggested in prior references (see, for example, paragraphs [0016]-[0017] in the specification of the present application), and the claimed lower levels are only made possible by an unexpected apparent synergy between the alcohol-based volatile biocide and the low-concentration, non-volatile antimicrobial agent components of the claimed compositions, as discussed for example in paragraphs [0037]-[0038], [0044]-[0045], [0058] and [0064]-[0066] of the specification of the present application. Such unexpected synergism results in the advantages of reduced exposure to these components and reduced cost for manufacture. There is no disclosure or suggestion of this in Scholz.

Therefore, for at least the above discussed reasons, independent Claims 1 and 9 and those claims dependent thereon are not disclosed or suggested by Scholz and are patentably distinct over this reference. Accordingly, it is respectfully requested that this rejection be withdrawn.

B. Scholz in view of Luu et al. (U.S. 5,871,763)

The Examiner also rejects Claims 1, 5-10, and 13-16 under 35 U.S.C. §103(a) as being unpatentable over Scholz (U.S. 5,908,619) in view of Luu et al. (U.S. 5,871,763). This rejection is also respectfully traversed.

As discussed *supra*, Scholz does not disclose or suggest the claimed compositions.

Further, there is no reason for one of ordinary skill in the art to combine the disclosure in Luu with Scholz to arrive at the claimed invention. Scholz concerns certain topical agents for direct application to the skin, whereas Luu concerns substrates (such as tissues) treated with certain lotions.

The Examiner provides no reason why one of ordinary skill in the art would be led to combine these unrelated compositions to arrive at Applicants' claimed compositions. This is a clear example of improper hindsight reconstruction using the claimed invention as a blueprint to combine the references.

More specifically, Luu concerns a lotion treated substrate, "preferably tissue, towel or napkin, optionally wet-strengthened, wipe or nonwoven material...." (Abstract) In describing the lotion, Luu notes that:

"The lotion can optionally include a therapeutic amount of a medicinal agent. Medicinal agents include medicines.... antimicrobial agents... and the like. For example, an antibacterial agent can be present in an amount of from about 0.01% to about 10%, preferably from about 0.05% to about 5%, of the lotion. Suitable antimicrobial agents include those effective against human pathogens.... Specific antimicrobial agents suitable for use in the lotion of the invention include 2,4,4'-trichloro-2'-hydroxydiphenyl ether (triclosan)...., chlorhexidine, chlorhexidine gluconate,...." (column 9, lines 24-47)

Several important points are relevant to this disclosure:

- As a key component of this lotion, Luu describes use of fatty alcohol esters and polyvinyl alcohols (i.e., emollients) throughout the specification, but makes no reference to or suggestion of a volatile alcohol. Thus, Luu does not describe a composition remotely related to Applicants' claimed compositions, which contain both a volatile alcohol and a non-volatile antimicrobial agent.

The composition of Luu is also unrelated to those of Scholz.

- Furthermore, the preceding reference to concentrations pertains to an extensive listing of antimicrobial agents (this list includes triclosan and CHG) which have a range of reported active concentrations. As in the case of Scholz, Luu teaches a "more is better" strategy to selection of concentration, stipulating that a level of "from about 0.05% to about 5%, of the lotion" is preferable.

- The composition in Luu is for treatment of a substrate (tissue, wipe, etc) so it is not possible to ascertain how this might apply to a composition for direct application to the skin.

Thus, the teachings in Luu are unrelated to Applicants' claimed compositions, and any relevance to Scholz with possible regard to Applicants' claimed compositions can only result from improper hindsight reconstruction. There must be reason for one skilled in the art to combine references to arrive at the claimed invention. See KSR International Co. v. Teleflex Inc., 550 USPQ2d 1385 (2007). It is not merely enough to note that all the elements of a claimed invention are known. As noted in KSR when explaining why a reason to combine references is important, "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." In this case, there is no reason to selectively combine a small portion of Luu's disclosure of certain emollient compositions for treatment of tissues with other portions of Scholz's disclosure to arrive at the claimed liquid bactericidal compositions of the present application. Rather, such a combination can only be based on improper hindsight reconstruction.

Finally, Applicants note that since Luu fails to include a volatile alcohol biocide, the compositions in Luu are unlikely to exhibit the antimicrobial synergy illustrated in the specification of the present application and the examples therein. Thus, one of ordinary skill in the art, upon attempting to adapt the teachings of Luu, is likely to conclude that much higher levels of triclosan are necessary (relative to those of Applicants' claimed invention) to achieve a desired biocidal effect, based either on the properties of triclosan as reported in the prior references or through experimentation with compositions conforming to the disclosure in Luu. Such practitioners would thus be led away from Applicants' compositions upon any application of the teachings of Luu.

Further, the Examiner contends that the claimed ranges are merely optimized through routine experimentation. This is incorrect. As explained *supra*, none of the references disclose or suggest the claimed range but are directed to increasing upward from the claimed range. Furthermore, Applicants have shown that an unexpected synergistic bactericidal result occurs with the claimed invention. This is not an optimized range through routine experimentation but an unexpected result. This overcomes any rejection based on an allegation of “optimization through routine experimentation.” See e.g. MPFP 2144.05.

Therefore, independent Claims 1 and 9 and those claims dependent thereon are not disclosed or suggested by Scholz in view of Luu, the combination of these references is improper, and Claims 1 and 9 and those claims dependent thereon are patentably distinct over these references. Accordingly, it is respectfully requested that this rejection be withdrawn.

### **Conclusion**

For at least the above-stated reasons, it is respectfully submitted that the claims of the present application are in an allowable condition and are patentable over the cited references. Accordingly, it is requested that the application now be allowed.

If any further fee should be due for this amendment, and/or the extension of time, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

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